The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte WINOK DEBYSER and JAN DELCOUR

Appeal 2006-3335
Application 09/403,625
Technology Center 1600

Decided: August 23, 2007

Before DEMETRA J. MILLS, LORA M. GREEN, RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

The Appellants appeal the Examiner's final rejection of claims 48-50, 52-56, and 65-68 for lack of written description. Claims 51 and 57 are objected to as being dependent upon a rejected base claim, but have been indicated by the Examiner to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. We have jurisdiction under 35 U.S.C. § 6(b) (2006).

The appealed claims read as follow:

48. An isolated protein or glycoprotein inhibitor of xylanase, which inhibitor is a water-soluble, alkaline protein or glycoprotein, which protein or glycoprotein comprises an N-terminal amino acid sequence which is at least 70% homologous to SEQ ID NO:1, said inhibitor having a pI of greater than about 7.0, and a molecular weight of about 40-43 kDa as measured by SDS-PAGE.

49. An isolated protein or glycoprotein inhibitor of xylanase, which inhibitor is a water-soluble, alkaline protein or glycoprotein, which protein or glycoprotein comprises an N-terminal amino acid sequence which is at least 70% homologous to SEQ ID NO:1, said inhibitor having a pl of greater than about 7.0 and a molecular weight of about 40-43 kDa as measured by SDS-PAGE, said inhibitor resolving as two separate bands on SDS-PAGE after reduction with β-mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and about 10 kDa.

50. The isolated protein or glycoprotein inhibitor of claim 48 wherein said protein or glycoprotein comprises an amino acid sequence of SEQ ID NO:1.

52. The isolated protein or glycoprotein inhibitor of claim 48 wherein said inhibitor is obtainable from a cereal plant, or cereal plant fraction thereof.

53. The isolated protein or glycoprotein inhibitor of claim 49 wherein said inhibitor is obtainable from a cereal plant, or cereal plant fraction thereof.

54. The isolated protein or glycoprotein inhibitor of claim 48 wherein said inhibitor is obtainable from a plant, or cereal plant fraction thereof, selected from the group consisting of wheat, rye, triticale, barley, sorghum, oats, maize and rice.

55. The isolated protein or glycoprotein inhibitor of claim 49 wherein said inhibitor is obtainable from a plant, or cereal plant fraction thereof, selected from the group consisting of wheat, rye, triticale, barley, sorghum, oats, maize and rice.

56. The isolated protein or glycoprotein inhibitor of claim 50 wherein said inhibitor is obtainable from a plant, or cereal plant fraction thereof, selected from the group consisting of wheat, rye, triticale, barley, sorghum, oats, maize and rice.

65. An isolated wheat protein or glycoprotein inhibitor of xylanase, which

inhibitor is a water-soluble, alkaline protein or glycoprotein, which protein or glycoprotein has a pl of greater than about 7.0 and has a molecular weight of about 40-43 kDa as measured by SDS-PAGE, said protein or glycoprotein being able to resolve as two separate bands on SDS-PAGE after reduction with β-mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and about 10 kDa.

66. An isolated cereal protein or glycoprotein inhibitor of xylanase, which inhibitor is a water-soluble, alkaline protein or glycoprotein, which protein or glycoprotein has a pl of greater than about 7.0 and has a molecular weight of about 40-43 kDa as measured by SDS-PAGE, said protein or glycoprotein being able to resolve as two separate bands on SDS-PAGE after reduction with β-mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and about 10 kDa, and wherein said cereal is selected from the group consisting of wheat, rye triticale, barley, sorghum, oats, maize and rice.

67. An isolated cereal protein or glycoprotein inhibitor of xylanase, which inhibitor is a water-soluble, alkaline protein or glycoprotein, which protein or glycoprotein has a pl of greater than about 7.0 and has a molecular weight of about 40-43 kDa as measured by SDS-PAGE, said protein or glycoprotein being able to resolve as two separate bands on SDS-PAGE after reduction with β-mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and about 10 kDa, and wherein said cereal is selected from the group consisting of wheat, rye and barley.

68. An isolated cereal proteinic or glycoproteinic inhibitor of xylanase, which inhibitor is a water-soluble, alkaline protein or glycoprotein, which protein or glycoprotein has a pl of greater than about 7.0 and has a molecular weight of 40-43 kDa as measured by SDS-PAGE and wherein when said cereal proteinic or glycoproteinic inhibitor of xylanase is a wheat proteinic or glycoproteinic inhibitor of xylanase said protein or glycoprotein is able to resolve as two separate bands on SDS-PAGE after reduction with β- -mercaptoethanol, said two separate bands having molecular weights of about 30 kDa and about 10 kDa.

DISCUSSION

The claims relate to a protein or glycoprotein which is an inhibitor of xylanase. These inhibitors are used in food, feed and/or beverage technologies, such as malting or brewing, the production of animal feedstuffs, the production of baked and/or extruded cereal products, pasta and noodles, and the production of starch derived syrups. The inhibitors are also used in the wheat gluten-starch separation industry and in pharmaceutical applications. (Spec. 1) The inventors found indications for xylanase inhibition of the xylanolytic barley malt system by wheat water extractables. (Spec. 8.)

The xylanase inhibitor may be present in cereal grains or fractions thereof, such as cereal germs, cereal flours from wheat, durum wheat, rye, triticale, barley, sorghum, oats, maize and rice. (Spec. 5, ll. 14-24.)

Written Description

Claims 48-50, 52-56, and 65-68 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. (Final Rejection 2)

The Examiner contends the claims lack written description because the "scope [of] the genus includes many proteins . . . with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists." (Answer 7-8.)

Appellants contend that the claims provide for proteins or glycoproteins described by various combinations of physical and chemical characteristics and that the Specification provides a structural and functional description of the claimed inhibitor proteins. (Br. 14, 22.)

More specifically, the Examiner finds

> The Specification describes a xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequences of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0.
>
> The Specification and sequence listing show that SEQ ID NO:1 is a sequence of 14 amino acids and SEQ ID NO: 2 is a sequence of 17 amino acids. It is known in the art that the average molecular mass of an amino acid residue in a protein is about 0.11 kDa (See Proteins: Structures and Molecular Properties, 2nd ed.(1993), Thomas E. Creighton, p. 4, Table 1.1). Thus, the described xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein having a molecular weight of 40-43 kDa is a protein that contains approximately 333-358 amino acid residues.

(Final Rejection 2-3.)

The Examiner succinctly concludes:

> The Specification only provides minimal amino acid sequence information that identifies 31 amino acid residues out of approximately 333-358 amino acid residues of the claimed protein xylanase inhibitor, as evident by the 14 amino acids in SEQ ID NO: 1 and 17 amino acids in SEQ ID NO: 2. No significant amino acid sequence and structure which is common to all members of the claimed genus has been described. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.
>
> Since the disclosure fails to describe the significant amino acid sequence and structure which is common to all members of the genus, and because the genus is highly variant, recitation of SEQ ID NO: 1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a

> representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

(Final Rejection 3.)

Claims 48-50 and 52-56

We agree with the Examiner that claims 48-50 and 52-56 do not possess adequate written description in the Specification.

We have selected claim 48 as representative because Appellants did not separately argue any claim within the grouping. Claim 48 is directed to a broad genus proteins or glycoproteins that act as xylanase inhibitors, but is unrestricted as to the source of the inhibitor or whether the inhibitor is naturally-occurring or an engineered variant.

In *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the court held that claims generically reciting cDNA encoding vertebrate or mammalian insulin were not adequately described by the disclosure of cDNA encoding rat insulin, and thus did not meet the requirement of adequate written description. *Id.* at 1568, 43 USPQ2d at 1406. The court held that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. The court held that a

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide

> sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. at 1569, 43 USPQ2d at 1406. The court has since clarified that the complete structure of the representative species does not necessarily have to be described. *See Enzo Biochem v. Gen-Probe*, 323 F.3d 956, 964-65, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

Eli Lilly supports our conclusion that the instant Specification does not adequately describe the recited genera of proteins/glycoproteins. The *Eli Lilly* court held that a fully described genus is one for which a person skilled in the art can "visualize or recognize the identity of the members of the genus." Here, as the Examiner has pointed out, the disclosure fails to describe the amino acid sequences and structure which is common to all members of the genus, and recitation of SEQ ID NO: 1 alone is insufficient to describe the genus as it provides the sequence for only a small portion of the protein. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

To describe a genus of functional variants (i.e., having xylanase inhibition activity), the Specification must provide guidance regarding which variants within the genus have the recited function. We find the Specification does not describe the recited genera sufficiently to allow a person skilled in the art to determine whether a given protein or glycoprotein variant is within the scope of the claims, thus the inventor was not in possession of the claimed subject matter at the time of filing. Claim 48 for example, recites a functional feature, that the protein is an inhibitor of xylanase, and then recites several generic characteristics which are descriptive proteins in general, but which hardly distinguish or define the claimed

protein as a xylanase inhibitor. In particular, claim 48 recites that the inhibitor is a protein or glycoprotein, is water- soluble, and is alkaline. These characteristics may be found in many proteins from many sources, and thus are non-distinguishing characteristics. Claim 48 recites several additional characteristics of the protein which are also representative of a larger genus of proteins. For example, the protein has an isoelectric constant of 7, has a molecular weight of 40-43 kDa and contains an N-terminal sequence (of 14 amino acids) that is 70% homologous to SEQ ID NO:1.

With respect to the written description requirement, while "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included "to demonstrate that the patentee possessed the full scope of the [claimed] invention." *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d. 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

Appellants acknowledge, "the present application not only describes proteinaceous xylanase inhibitors present in plants ..., but also teaches the isolation from wheat, barley and rye." (Br. 19) Thus, Appellants acknowledge the broad claims in the application encompass more than xylanases found in cereal plants or even plants.

In our view, these claims cover a very broad genus of xylanase proteins which could be found in a broad group of microorganisms, fungi or plants. Appellants acknowledge the broad claims in the application encompass more than xylanases found in cereal plants (Br. 19). Appellants have not described a representative number of species within the broad genus that possess similar structural identifying characteristics that would allow the skilled artisan to discern other members of the genus.

Appellants argue that the percent homology to SEQ ID NO:1 is a structural limitation common to the members of the group of xylanases, however, this sequence is only a small portion of a much larger protein sequence. Appellants have not provided any information that the recited sequence is necessary for the functional activity of the claimed inhibitor, and thus is not descriptive of the genus as required under *Lilly*.

We do not agree with appellants that the broad claims are limited in any way to cereal plants. (Br. 10, 19.) In view of the above, the rejection of claims 48-50 for lack of written description is affirmed.

Claim 65

Appellants separately argue claim 65, asserting that "the specification exemplifies a wheat xylanase inhibitor such that the further recitation of SEQ ID NO:1 and SEQ ID NO:2, in addition to the eight (8) characterizing features of claim 65 should not be required" (Br. 31).

We do not agree. In the "Summary of the invention," beginning on page 4 of the Specification, the invention is characterized as a xylanase inhibitor with the following characteristics, including: 1) water soluble; 2) a pI of about 7; 3) molecular weight of about 40-43 kDa; 4) resolves into two bands following reduction; and 5) a specific N-terminal sequences of SEQ ID NOS: 1 and 2 (Spec. 5: l. 25 to 6:10). Appellants state that "[t]he N-terminal sequence . . . has not been described until now" (Spec. 5: 31 to 6: 1). Additional embodiments in the "Summary of the invention" are also described by the presence of SEQ ID NO: 1 or 2, or sequences having identity to them (Spec. 6: 11-31). In our opinion, persons of skill in the art reading the Specification would have recognized that Appellants describe a genus of inhibitors of isolated from natural sources which

are characterized by the presence of SEQ ID NOS: 1 and 2, in addition to the other identifying characteristics. We do not find a basis in the "Summary of the invention" for a broader genus of proteins that lacks the distinguishing sequence information that Appellants declare to have discovered. Thus, the Specification does not convey possession of the genus claimed in claim 65. At least for this reason, we do not find the claim in compliance with 112, first paragraph.

Claims 66, 67, and 68

Appellants argued claims 66, 67, and 68 separately, relying on the same arguments as for claim 65 (Br. 31-32). Since none of these claims contain the sequence limitation, for the reasons set forth above, we also do not find that these claims comply with the written description requirement of 112, first paragraph.

Other Issue for Consideration

It is recommended that the Examiner reconsider whether a written description rejection should be made with respect to allowed claims 51 and 57, in view of this decision.

CONCLUSION

The written description rejection of claims 48-50 is affirmed. The written description rejection of claims 52-56 and 65-68 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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